HEALTH, COMMUNITIES, DISABILITY SERVICES AND DOMESTIC AND FAMILY VIOLENCE PREVENTION COMMITTEE

Members present:

Ms L Linard MP (Chair)
Mr MF McArdle MP
Mr SE Cramp MP
Mr AD Harper MP
Mr D Janetzki MP
Mr JP Kelly MP

Staff present:

Mr K Holden (Research Director)
Mr J Gilchrist (Principal Research Officer)

PUBLIC HEARING—INQUIRY INTO THE PUBLIC HEALTH (MEDICINAL CANNABIS) BILL 2016

TRANSCRIPT OF PROCEEDINGS

MONDAY, 29 AUGUST 2016

Brisbane

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Committee met at 9.00 am

CHAIR: I declare open this public hearing of the Health, Communities, Disabilities Services and Domestic and Family Violence Prevention Committee's inquiry into the Public Health (Medicinal Cannabis) Bill 2016. I acknowledge the traditional owners of the land on which we meet and pay my respects to elders past, present and emerging. My name is Leanne Linard. I am the chair of the committee and member for Nudgee. The other members of the committee are Mr Mark McArdle, deputy chair and member for Caloundra; Mr Aaron Harper, the member for Thuringowa; Mr Sidney Cramp, the member for Gaven; Mr David Janetzki, the member for Toowoomba South; and Mr Joe Kelly, the member for Greenslopes, who will join us soon. The bill was referred to the committee on 10 May 2016. The purpose of this hearing is to receive additional information from stakeholders to assist us in our examination of the bill.

There are a few procedural matters before we start. The committee is a statutory committee of the Queensland parliament and, as such, represents the parliament. It is an all-party committee that takes a nonpartisan approach to inquiries. This hearing is a formal proceeding of the parliament and is subject to the Legislative Assembly's standing rules and orders. The committee will not require evidence to be given under oath, but I remind everyone that intentionally misleading the committee is a serious offence. You have been provided with a copy of the instructions for witnesses, so we will take those as read. Hansard will record the proceedings and you will be provided with a copy of the transcript. This hearing is being broadcast and is to be used as part of parliamentary education training. I will invite each witness to make a brief opening statement of up to five minutes and members will then ask questions.

LINTZERIS, Conjoint Professor Nicholas, Royal Australasian College of Physicians (via teleconference)

CHAIR: First, we have Conjoint Professor Nicholas Lintzeris—I hope I have your name right, Professor—from the Royal Australasian College of Physicians. Thank you for joining us via teleconference.

Prof. Lintzeris: Thank you.

CHAIR: Would you like to make a brief opening statement and then committee members will ask questions?

Prof. Lintzeris: Briefly, the College of Physicians has made a submission to the parliamentary inquiry. Overall, we support the intent of the bill. We have some concerns around some of the specifics, but the college generally supports the intent of the proposed bill.

CHAIR: I am sorry, Professor, but we are trying to work on a small sound issue at our end. I understand that you have just indicated your support for the intent of the bill. Would you like to make any further comments before we ask questions?

Prof. Lintzeris: Because of the telecommunications, I might go straight to questions rather than try to initiate a discussion at my end.

CHAIR: Thank you. The opening comment or statement from the college talks about the support of the college for developing an evidence base for the use of medicinal cannabis. Do you have any comments to make in regard to the evidence that already exists in international jurisdictions, as well as domestically? The committee has certainly received some commentary about the fact that some feel there is already a significant evidence base around the efficacy of using medicinal cannabis.

Prof. Lintzeris: Firstly, we need to identify what we mean by 'medicinal cannabis'. There are many different types of cannabinoid medicines. Some of them may well be just whole plants. People vaporise and smoke the whole plant. We have pharmaceutically developed medicines, distilled from the whole plant, such as Sativex or nabiximols. There are different cannabinoids such as cannabidiol, which is CBD, also derived from the cannabis plant and technically a medical cannabis product, but it does not have any of the THC products. There is a wide variety of medical cannabis products.

As regards the evidence base, it very much depends on which condition and which type of medical product. There already is, for example, sufficient evidence in Australia that has led the TGA to license the use of nabiximols or Sativex for multiple sclerosis. Likewise, that medicine has been licensed in, I think, about 15 countries for multiple sclerosis. There is also a range of cannabinoid medicines—such as dronabinol or nabilone—in other countries and jurisdictions that have been licensed for specific indications, such as chemotherapy induced nausea and vomiting, and certain palliative care settings, what used to be associated with AIDS and cancer. There is already an existing evidence base. However, there are increasing arguments for the expansion of cannabis products outside of those somewhat limited indications, with particular interest in the areas of epilepsy, chronic pain, sleep disorders and a range of mental health conditions such as post-traumatic stress disorder. For each of those there is emerging evidence, in some areas better than others, such as chronic pain, which already has a substantial evidence base suggesting cannabinoids may have a role there.

We also need to appreciate the position of the college. Within medicine, we actually demand a specific evidence base that meets the standards which medicine is expected to apply to. We generally want well-conducted studies, generally in the form of randomised control trials. Generally we want those studies to have been replicated, so not just relying on one study. Generally we want to see those findings replicated in two, three or more randomised control studies and then we go and do a meta-analysis on that evidence to come up with the synthesis of what the research tells us. It is fair to say that in many conditions we just do not have that breadth of evidence around specific cannabis products. This is somewhat different to the community perception that cannabis has been used for many thousands of years and we know that it works. There is a distance; there is a gap between often what we see within the community and expectations or people's own personal experience, compared to the level of evidence that the college and regulatory bodies such as the TGA would like to see.

CHAIR: Thank you, Professor, for those comments. I move to point 2 in the submission. There is a comment there in response to the concerns that the college has about the use of medicinal cannabis. The comment is made that managing the risk of harm and minimising opportunities for misuse is another concern expressed by members of the RACP. This includes concerns about the appropriateness of using medicinal cannabis in patients with addiction and metal health issues. For the benefit of the committee, can you talk about how the college's concerns in this regard are different from the concerns that may be held about the use of opiates for the same vulnerable group?

Prof. Lintzeris: Certainly. My specific background is as an addiction medicine specialist. This is an area that I spend some time thinking about and a field that I work in, including the misuse of prescription medications including opioids and benzodiazepines. Essentially, we are saying that cannabinoids, just like a range of other medicines, can have potential benefits but they can also have potential adverse effects or harms. Some of those may include the development of addiction, and that can happen with cannabis. It appears to happen in the minority of individuals. By no means will the majority of individuals who use cannabis go on to become dependent. That is the same, pretty much, for most medicines that we use.

There are also other safety concerns around cannabis based products, and that is especially so with the THC based products. Some of those can be associated with intoxication and sedation. That could be associated with things such as falls and motor vehicle accidents. That is also consistent with any psychoactive medication that may cause intoxication, including opioids, benzodiazepines, antidepressants and so forth. Cannabinoids also potentially have the risks, in a small proportion of patients, of mental health problems, in particular anxiety, paranoia and, in a small number of cases, psychosis. Those are also meant to be monitored and that is another reason we would not propose the wide-scale availability of cannabis based products outside of a medical framework.

However, whilst we can identify that there are these harms, we also need to not overstate the potential harms associated with cannabis. The cannabinoid medicines, whilst there are those harms I just described, generally tend to be a relatively safe range of medications in regard to overdose and respiratory depression. There are many people from the Americas, the US and Canada who have highlighted that in those jurisdictions where medical cannabis is available and widely used for the treatment of chronic pain there has been a reduction in prescription opioid related deaths. That has led some to argue for us to reconsider the way that we are treating chronic pain, to move away from a reliance on prescription opioids to increasing the use of medical cannabis based products. The evidence for that is what we would call epidemiological. It is looking at larger populations. There could be a range of factors that could cause the findings that have been reported.

As yet, we do not have well-constructed studies to be able to demonstrate that patients on medical cannabis end up using lower amounts of prescription opioids or have lower rates of overdose. This is a very interesting and promising area for us to develop. Again, the evidence and the data is not available for us to be able to conclusively make those statements at this time.

CHAIR: Professor, in your submission you draw the distinction between a specialist being able to prescribe medicinal cannabis and a GP. You have raised concerns in that regard. I believe it is correct that a GP can currently prescribe schedule 8 drugs such as OxyContin or the other opioids that you have commented on. Is it your belief that they should not be able to prescribe medicinal cannabis because it is not as well understood as the effects that could arise out of those other schedule 8s? Is that correct or not?

Prof. Lintzeris: We will see where we end up in 10 or 20 years time once we have a licensed medicine with a sound evidence base. Overall, the cannabinoids are not particularly complicated medicines or particularly dangerous medicines; it is just that, whilst we are talking about unlicensed medicines with a poor evidence base, there is a potential for doctors who are not specialists in particular conditions to end up setting themselves up as cannabis medicine specialists as opposed to doctors who have expertise in the treatment of a particular condition.

Some of this is really more about transitioning from how we might start using cannabis medicine to where we may end up using cannabis medicine. I do not think in the balance of things that medical cannabis or cannabinoid medicines are that dangerous that in the long run we will end up having to limit it to only specially trained doctors, but we need to consider how we embark on setting up a system.

Mr McARDLE: Thank you very kindly for being with us by telephone today. I will take the last point raised by the chair a bit further. Do you see a transition being put in place whereby at the start it should be specialist medical practitioners who are involved with the process under the Queensland act and as time goes by and that process and the efficacy of the drug that is prescribed become clearer and more certain then it could be pushed down to general practitioners in the suburbs?

Prof. Lintzeris: That is a good summary—exactly. Often when we start an area of medicine we do have to set things up in such a way that we ring-fence it; we make sure that our practitioners have particular skills and we pay greater attention to how we do it. The systems by which we will be providing cannabis based medicine will look very different in 10 to 15 years times to how we start off in the next few years.

Mr McARDLE: As I understand it, the special access scheme under the TGA allows a practitioner—and I do not think 'practitioner' is defined—to make an application to the special access scheme. With regard to this bill in Queensland, there have been claims of an overlap between the process being put in place here and the TGA model. Can you comment on that given your background in this area and your knowledge of the TGA with regard to the special access scheme?

Prof. Lintzeris: It really speaks to the different reach of a state versus a federal regulatory system. We have lots of examples of unlicensed medicines where the special access scheme within the TGA framework would not necessarily specify a particular type of doctor. That then often falls to the state level. I can give you the example of prescribing methadone for treating addiction. That is not specified at a federal level as to what kind of doctor can do that, but the states implement their own regulations that then say only specific credentialed doctors who have gone through a training program, for example, may prescribe that medicine.

There is nothing necessarily unusual about the idea that at a state level there may be a different orientation as to how they organise their health system and medical workforce. We clearly have some very real issues about the practicality of the current system that has been put in place at a federal and state level. What I mean by that is that for any patient to realistically embark upon the special access scheme program or the authorised prescriber program—they are the two mechanisms by which unlicensed medicines can be given in Australia—it is a particularly unwieldy process. It is a process that will take months to negotiate.

A patient has to find a doctor who is prepared to make the application for special access, have that reviewed by the TGA, then have the same issues reconsidered at a state level. That is then before we start addressing issues about how we import the medicine into Australia. On our reckoning, we think it is highly unlikely that any patients embarking on this process could actually achieve having medical cannabis products within three to six months of application. In some circumstances that three- to six-month wait may be clinically inappropriate. For example, in a palliative care setting, saying to a patient that it is going to take three to six months to process the application is clinically inappropriate.

Mr McARDLE: We are having Queensland Health attend later in the day. Under the Queensland bill, a patient can go to a doctor and the process can be put in place under the Queensland legislation. At the end of the day, however, the doctor still has to seek TGA approval under the special access scheme to obtain access to the drug. Is it the case under the state legislation that the prescriber goes to the TGA and then the TGA undertakes its own review of the process and the efficacy of the drug to be issued to the patient, or is that not the case?

Prof. Lintzeris: The TGA really does not have the expertise to make that review—that is, to get all the evidence from the doctors, to have a broad multidisciplinary panel assess it and to review the medicine itself. Really what we need is probably a separation of different parts of government to take on the responsibility of reviewing different components of the system. For example, someone has to review the safety of the proposed medicine. Has the cannabis medicine been reviewed by an appropriate group of experts that can determine that the medicine will be safe, will be reliable, is not contaminated with pesticides or fungal infections? We want to know about the quality of the medicine.

We want to know about the details of the treatment provider. There are specific issues around the patients themselves: what is the severity of the disorder, what has been tried before, how will we know whether or not the medicine works on this occasion, how do we propose to monitor the condition to see whether or not things are improving and whether treatment should be continued? There is a range of different aspects of this approval process that we need to get right. At the moment they are replicated at a state and federal level without good harmonisation of the process.

Mr KELLY: From listening to your evidence this morning and from looking at your submission, it seems that what you are effectively saying is that we should treat medical cannabis as we treat every other medication in Australia. Is that correct? Is that fair to say?

Prof. Lintzeris: There are some fundamental principles about how we approach the regulation of medicines. They should also be applied to cannabis. There are some idiosyncrasies to cannabis that make it somewhat complicated in understanding how we roll it out. That is partly because it is a plant based product and partly because we are coming out of 50 years of prohibition, where we have had a regulatory framework which prevented us from using medical cannabis. Part of it is the drug itself; part of it is our legal history. The basic principles about how we regulate medicines and how we select which medicine gets used for which patient are fundamental principles that we should not stray far from.

Mr KELLY: We have a research brief that lists the approaches to medical cannabis taken in 25 states in the US and Washington DC as well as in a couple of other countries. In your view or in the view of your college, is there any legislature overseas that is dealing with medical cannabis in a way that is applying those broad principles that you are talking about?

Prof. Lintzeris: Can you repeat the question, please?

Mr KELLY: There are 25 states in the United States that have legislated for medical cannabis and additionally Washington DC. There are a number of other countries that we have had some information on as well. Is your college aware of how those countries have legislated? Are they applying those broad principles that you are talking about in relation to dealing with any medicine?

Prof. Lintzeris: Within the US there is no federal approval of medical cannabis. Medical cannabis remains illicit or illegal in the United States. What we have in the United States is that individual states have gone and passed their own legislation. They vary considerably. For some of them it is medical cannabis only in name in the sense that doctors are not involved in prescribing or supplying. Essentially, patients go and get a letter from a doctor saying that they have a medical condition and that allows them to buy cannabis from a distributor. That is not really a medical framework that we are describing.

In other parts of the US they have set up different regulatory models. In the more recent examples, in jurisdictions such as New York and Florida, they have something that is more consistent with what we consider medicine. There are a number of named conditions, there are specific products that can be prescribed and there are doctors prescribing for specific patients. They get a state regulatory approval. The US varies considerably.

Canada has gone down the way of a joint model. On the one hand there has been a wide proliferation of pharmaceutical cannabinoid products—medications such as Dronabinol, Nabilone and Sativex. They have also allowed medical cannabis dispensaries. Different parts of Europe have different models.

What we are generally seeing is an increasing worldwide trend of medical cannabis becoming available. Different jurisdictions are trying to understand how they can get this balance of, on the one hand, meeting a strong political and consumer demand and expectation while, on the other hand,

trying to understand whether there is a way of regulating this which puts it within a medical framework as opposed to a decriminalisation model. I think it is fair to say that the early attempts in the US were really more about a decriminalisation model than a medical model. It is about getting the balance right.

Mr JANETZKI: I have a couple of questions about the general thrust of the college's position. Is it correct that the college's position is supportive of medicinal cannabis in clinical trials and you would be otherwise reserving your judgement on the appropriateness of this bill until such further evidence has been ascertained?

Prof. Lintzeris: In terms of the widespread availability of medical cannabis, I think what we want to see is better evidence. That generally means getting the trials either from overseas or here. We also recognise that for specific individual cases—and this is the way medicine operates—there may well be a role for the use of an unlicensed medicine where there is a strong individual need that can be demonstrated and where other forms of treatment have not proved to be effective.

In other areas of medicine there is a framework to enable that, and that is the special access scheme and so forth. Within the world of medical cannabis, because of the regulatory difficulties around cannabis and the history of it being a prohibited substance, we have had to create these new bills or regulatory adjustments to enable that kind of special access or individual availability based on individual need. That requires some checks and balances. It requires an expert panel to make decisions where the evidence base is not clear. It requires regulators to be able to assess the safety of medicines and so forth. The thrust of the bill we are generally supportive of. We would not like to see widespread availability of medical cannabis as a front-line treatment at this stage, until there is better evidence of safety and efficacy.

Mr JANETZKI: In terms of that better evidence, for instance, in your submission you talk about evidence emerging about the epileptic condition. Do you have any idea of the time frame in which this emerging evidence may be medically sustainable or when the college may be in a position to form a firm view as to the efficacy of the research?

Prof. Lintzeris: There are two large randomised controlled trials that are being completed. One has been completed and has been reported at conference. That information is publicly available but it has not gone to peer review yet. There is one other trial that we are expecting in the next few months, when that data should also become available. We are expecting within the next three to six months the publication of two large randomised controlled trials that will be the first controlled study in epilepsy. We expect that this calendar year we will have a better understanding of the role there. Of course there are what we call uncontrolled studies of some medications, and that is CBD. That is a non-THC, a non-intoxicating, medical cannabis. There are patients being treated under authority prescriber models here in Australia. That has already started. My understanding is that there is also an attempt to set up a similar system in Queensland.

CHAIR: Professor Lintzeris, thank you very much for making yourself available this morning. Can you please take the thanks of the committee back to the college for their submission and the expertise of the college and to yourself for assisting the committee. Thank you very much for your time.

FINN, Dr Jim, Australian Medical Association Queensland

CHAIR: Dr Finn, welcome and thank you for making yourself available this morning. I appreciate your patience. I invite you to make an opening statement of up to five minutes and then we will open it up to questions.

Dr Finn: The Australian Medical Association Queensland represents approximately 6,000 doctors throughout the state. We are very grateful that we have an opportunity to comment on the cannabis bill within Queensland. We see it as an opportunity to further investigate both the efficacy and the safety of cannabis derived products in rescheduling cannabis from a section 9 prohibited drug to a section 8 controlled medication. Many other substances, such as cocaine and opioids, are in section 8. For example, cocaine is used in operations to stem nasal bleeding in ENT surgery and by emergency physicians for the same purpose for vasoconstriction. It is used by dentists in lidocaine and novocaine. A substance like that is a controlled substance with its derivatives, as are other derivatives of the opium poppy in use as morphine and oxycodone for adequate purposes within Queensland. For a long period of time derivatives of cannabinoids have been completely prohibited. The AMA sees this bill as an opportunity for research to be performed into cannabinoids to determine their efficacy and safety, which at the moment is still an open question.

CHAIR: Dr Finn, in regard to comments in other submissions about the fact that specialists should be the only ones to be able to apply through the pathways to prescribe medicinal cannabis, rather than GPs, can you provide any comment on that?

Dr Finn: Initially in the rollout of any new medication it is very useful to have a restriction on the group of doctors within subspecialities; for example, oncologists, paediatric neurologists and palliative care specialists—those specialists who would most likely be able to participate in clinical trials and have the initial interest in that particular area, because it in those three areas that medical cannabinoid products would probably have the most initial promise. That does not mean that other medical practitioners could not necessarily prescribe, but the initiating medication of the overall treatment program should be under a subspecialist with the correct credentialing.

CHAIR: Out of interest—I am sure you would have had discussions with general practitioners—what is the attitude towards medicinal cannabis?

Dr Finn: In discussing this with our general practitioner members, they are very keen to follow only evidence based medicine. At the moment we think there may be some promising studies coming through, but most of them, before initiating the cannabinoid product, would like to see double-blind randomised controlled trials and the efficacy of same.

CHAIR: There have been some concerns about the time delay that may occur in accessing the products, particularly around palliative care and those who may be time limited. Does the association have any views about that?

Dr Finn: If palliative care physicians had more open access than other medical practitioners, it could remove a lot of the time delay in that we do things in palliative care we would not do in normal prescribing. Our main concern in palliative care is always to relieve pain—both physical and emotional pain—that the patient is experiencing. For that reason, the longer term sequelae and side effects of the drug are of less interest. That, in my opinion, is the reason palliative care physicians should be some of the earliest to adopt and doctors and even general practitioners engaged in palliative care under the direction of a palliative care physician.

CHAIR: Is it your view, therefore, that those in that area of palliative care medicine should have some different process to the one proposed under the bill?

Dr Finn: No. It is just that they should be one of the three initial groups of physicians.

CHAIR: But they should still follow that process through?

Dr Finn: Yes.

Mr CRAMP: Thank you, Dr Finn, for coming in today. In the second last paragraph of your submission you talk about doctors being authorised and obviously potential recourse for doctors who are not authorised to prescribe medical cannabis. If we moved to the stage where the bill is purporting to provide GPs with that authorisation, does the AMA have any formative views at the moment about how authorisation would be provided to a GP?

Dr Finn: There are two different methods that could be performed. We could run through, say, an opioid prescribing type course, where the doctor would do a one- or two-day course to learn how to prescribe, as they do now for methadone and similar drugs. The alternative would be that no such course is required and we just allow our GPs open access to same. My reading of the actual bill itself,

however, is that one would have to be an authorised prescriber to actually do so. One would assume that if one did not have a subspeciality in one of the three physician areas one might have to do a course just on the legislation and on the parameters of the prescribing. That course could be internet based. It would not necessarily be a sit-down course, because these are experienced professionals who could self-educate.

Mr CRAMP: We listened to some witnesses last week who were either themselves a patient with an ongoing medical condition or a carer. They were talking about the fact that, whilst the AMA and several other peak bodies are looking at a pharmaceutical based system where it is sanctioned and controlled through regulation, they need varying levels of chemicals in what they utilise with cannabinoid products. What are your thoughts on people growing their own, as in some states in America and Canada, as opposed to having a prescription based system through authorised doctors?

Dr Finn: We see a duality in Australia. There are two different forces at play. One is the concept of self-medicating with homegrown cannabis and the second is pharmaceutical grade products. We have grave concerns about the concept of growing your own marijuana at home to self-medicate. For example, between 1978 and 2006 the level of cannabinoids in most marijuana supplied to recreational users illicitly has decreased and the amount of THC has gone through the roof, and that is one of reasons we have seen higher degrees of psychosis amongst cannabis smokers. Our concern is that, if people are growing their own variety, there is no quality control over which combination of cannabinoids they are getting in the product which tend to have an anti-psychotic effect—the THC level of the product, which traditionally illicit recreational growers have tended to favour and hybridly breed for. There is also no control over the storage of the product. Most pharmaceuticals have to have either a cold chain or a chain of moderate temperature. If people are recreationally or even for medicinal purposes breeding their own plants, it reduces the quality control, in our opinion, to too high a degree. We believe that if cannabinoid products are used they should be of medicinal grade and TGA approved.

Mr CRAMP: I am quite interested in the fact that potentially there is a domestic industry here if it is done properly. The previous witness spoke about importing the product for prescription based dispersion. What would be the AMA's view on growing product here in Queensland? Would that provide more control and oversight, in the AMA's view, of what we provide to our patients here in this state or do you think it is non-consequential whether we get it domestically or internationally?

Dr Finn: I think from an Australian industry point of view it would be wonderful to grow it in Queensland for pharmaceutical use. Australia is one of the world's leading producers of opioid products on Tasmanian farms. We have a very long tradition of probity and quality control of the substances. I think Australia would be a wonderful place to grow these substances for quality control. Provided the cannabinoid derivative pharmaceutical products were made in a major overseas lab, quality control in the First World tends to be fairly high but it is always nice to produce things in Australia.

CHAIR: Dr Finn, you cited some statistics. Are you able to provide us with the source? You were talking about from 1978 to 2006. You mentioned the quality and grade. That is very helpful for us as well.

Dr Finn: I do not have the source at my fingertips but I can email it through to the committee. There is a huge amount of research in how the nature of cannabis smoked has changed in Australia.

CHAIR: That is helpful for us. If you can email that to us, that would be lovely.

Mr HARPER: Good morning, Doctor. Thank you very much for your submission. I have a question in regard to the cost of medicinal cannabis. I have talked to some families in my electorate—one in particular—about the cost of medicinal cannabis if this bill is passed as it will not be listed on the PBS, potentially making it very expensive. This particular family has a child with drug resistant epilepsy. Do you have any concerns about cost and the take-up of medicinal cannabis in terms of that particular cohort or terminally ill patients? I get that a lot of you are saying a lot more research needs to be done in terms of an evidence base, and we will get there at a point in time, but we are going ahead with the proposed bill for a trial. Do you have any concerns around the cost of it?

Dr Finn: It is typical in medical trials for the participants in the trial to be provided with the product at no cost because they are giving back something to the wider community. One way of accessing an as-yet unproven medication is to go onto a trial and get the medication for free. That is a typical way to do it. However, to be valid at the highest level of validity, most trials do require a comparison of placebo effects, because a placebo effect, particularly with gravely ill individuals, can be up to 30 per cent. You can get a very strong placebo effect, but I think that is a very important equity issue.

Mr HARPER: I agree. Can you articulate your thoughts on who should be on the expert advisory panel?

Dr Finn: I think the previous speaker, Dr Nicholas Lintzeris, would be a wonderful addition. He is one of the doyens of addiction medicine in Australia. He would be very useful. I think the clinical director of ATODS in metro north, Dr Jeremy Hayllar, would be a very useful addition. As well as that, a paediatric neurologist might be very useful to be on the panel to provide a breadth of view.

Mr McARDLE: Dr Finn, thank you very much for coming in this morning. I only have one question and it relates to children under the age of 18 years who have epilepsy. There is a lot of argument about prescribing, or trials of, medical cannabis for children with epilepsy. Can we focus on trials? In their submission the College of Physicians raised the point that trials should be the only circumstance at this point in time under which this drug should be given to children under the age of 18 years. Do you agree with that? Do you agree that we are dealing with a very young child—a young body, a young mind—and to push it out beyond a trial at this point in time is not warranted until more data and evidence is collected and then understood?

Dr Finn: I would agree with that. My reason for agreeing is that the lowest level of evidence in medicine is expert opinion. That is level 6. A medical specialist may think it would be efficacious, but we often get things wrong. There have been numerous trials done where the expected outcome is the opposite of what we anticipate. We may think medical cannabis is doing this epileptic child a service but in a randomised controlled trial that may not be what is occurring. If we were looking at purely evidence based medicine, when a drug is unproven it should be tested first in a trial. That is not to negate the fact that there is already this special access program where everything else has been tried and this medication could then be tried on that child when other things have failed or other things are inappropriate.

The difficulty we have is that trials give us an aggregate average effect across the community. Because human beings have fluctuating genotypes and phenotypes, while a medicine may or may not work for the majority, for an individual it can be highly efficacious. If you roll something out, you want evidence that it works, as supported by a trial, but for a particular individual they may be atypical and the best person to determine that would be a subspecialist in the area treating that.

Mr McARDLE: You would argue, then, that the expert panel in relation to children and epilepsy should cover a range of experiences and experts as well? Given that a young child's mind and body are still developing for many years post the drug being administered, do you think a general practitioner would be very concerned about being involved in a process that could have a disastrous outcome when the child hits puberty or a bit older? The mind and body change dramatically in teenage years.

Dr Finn: I would 100 per cent agree with that. Many years ago I used to be a general practitioner, and I would say that we tend to be guided by our specialist colleagues in a particular area. There is a general rule in general practice that if there is a new treatment you do not want to be in the first five per cent or the last five per cent to use it. You want to be in the 90 per cent and you want to have the majority of your specialist colleagues concurring that it is the appropriate treatment. When there is a new treatment initially out, we often talk about the clinical leaders in that role, and they are different subspecialists who pioneer the treatment, run through the trials and later it is rolled out into general practice when it becomes more mainstream.

Mr McARDLE: You may have heard the question I posed to the professor on the telephone. I said to him, in essence: should we start with those who are expert in the field and, as time goes by, lead it down through the GP cohort? I am not being disrespectful to them, but they are not experts in the area of medicine with which we are dealing. Would you agree with that?

Dr Finn: I would agree. General practitioners are specialist doctors, but they are specialist doctors who have such a breadth of knowledge that it is impossible to be a subspecialist in everything, which is why we have subspecialisation. It is difficult, certainly in the initial stages, for a general practitioner to keep abreast of things. However, having said that, some general practitioners do have a subarea of interest and in a way tend to subspecialise themselves. There may be a minority of general practitioners who feel they have the expertise or the linkages with specialists in paediatric neurology to be co-prescribers.

Mr McARDLE: Thank you very much.

Mr KELLY: Dr Finn, constituents and people in the community have approached me and said, 'We are already using medical marijuana in one form or another. Why can't we take this information in relation to our child'—if they are treating a child for something like Dravet syndrome—'and add that to the general body of knowledge and consider that as part of the research and evidence?' Could you step us through if that is possible and how that would fit into a broader research process?

Dr Finn: Absolutely. The parallel would probably be when methadone first came into use by addiction specialists to treat heroin dependence. It was not through an initial trial. Heroin dependent people in the 1960s and 1970s in New York started accessing methadone to get themselves off heroin. Medical specialists then started looking at that and they ran a trial to see if the anecdotal evidence did work. That has been one of the most successful trials in addiction ever. The anecdotal evidence from these consumers is anecdotal evidence that should prompt us to a trial but not to entirely replace a trial, because an aggregate of anecdotal evidence mathematically in something like the Cochrane Collaboration cannot replace a randomised trial.

Mr KELLY: In your submission, in the fourth paragraph, the AMA raises concerns about the fact that the rescheduling has not occurred. What are the implications for us in terms of passing this bill if that rescheduling does not occur?

Dr Finn: As I understand it, the bill would still be valid but the rescheduling would have to occur as a tidying-up effect because of the 1996 poisons act. Our understanding was that it was going to be performed as a matter of urgency, but it would, in our opinion, mean that the cannabis had two different statuses.

Mr KELLY: You have already given your thoughts in relation to people growing their own product at home. We have had suggestions made via submission and also in evidence that there should be some sort of special testing regime set up just for marijuana so people can grow it at home and feel assured of the quality. What are your thoughts on establishing a specialised testing regime for one particular product?

Dr Finn: My thoughts are that it would be more efficacious and cheaper to supply people with a pharmaceutical grade product, rather than require them to grow their own. For example, if someone needed an opioid derivative for pain relief, we would not get them to grow opium poppies in their own backyard; we would give them pharmaceutical grade drugs. One could do a testing regime but the argument then is: what happens if one finds the product is high in THC and low in the appropriate cannabinoids? What is the growth cycle? Where do they source something in cannabinoids? It is much easier to supply the individual with an appropriate product.

Mr KELLY: I found it interesting when you mentioned earlier the changes in the contents of marijuana since the seventies and said that that is well documented via evidence. The notion is often put that marijuana is harmless. What does the evidence say in relation to marijuana, particularly the THC component?

Dr Finn: There is a correlation between daily marijuana use and psychosis. There is still a debate in the literature whether it is causation. As the number of telephone poles in the United States has increased over the last century, the number of obese Americans has increased. That is a correlation; it is not causation. We know that marijuana smokers, particularly smokers of marijuana of recent decades, tend to have a higher incidence of psychosis. In the literature it is debated whether this unmasks an underlying psychosis earlier or whether it is causative. We do think high levels of THC use are probably causative of psychosis but that is not yet 100 per cent supported in the literature. Similarly, we know that marijuana with high levels of cannabinoids tends to have a far less chance, and there is some thought that they are an antipsychotic contribution of the drug.

Mr JANETZKI: What consultation did the AMAQ undertake with its members to reach its position this morning?

Dr Finn: We did not consult our wider membership. The consultation to this view went through the board of the AMAQ and the council. There are nine board directors, of whom I am one, and 27 councillors. We relied on that rather than a poll of all our members because of the short time constraints we had in following up.

CHAIR: Our time for questions has expired. Dr Finn, thank you very much for coming this morning. Can you please pass our committee's thanks back to the association. They always make submissions to our inquiries and we appreciate it.

BOWEN, Mr Timothy, Senior Solicitor, Advocacy Claims & Education, MIGA (via teleconference)

CHAIR: Thank you very much for joining us this morning. Present with me here are my fellow committee members. Thank you for the submission that you have made. I invite you to make an opening statement of up to five minutes and then the committee will ask you some questions about the bill.

Mr Bowen: Certainly. I would like to thank the committee for the opportunity to be involved in this process. Our interest is on behalf of our membership and our insureds. We look after a significant number of doctors in Queensland and more broadly in Australia who may come across a regime similar to this. In our submission we have sought to look at the issues which might arise with this regime if it is passed. Some of the concerns we had were around unnecessary processes, but some of that has been dealt with by the introduction of patient class prescribers.

We also had some reservations around the degree of investigation of suitability of prescribers and patients, whether they are appropriate people to receive or be involved in this process and how the unforeseen is dealt with. When applications are rejected, where does that leave a patient if a practitioner is unable to continue being involved or if there is a need to expedite approvals? We also had some concerns around the criminalisation of potential conduct, particularly around the edges if there may have been a failure to complete documentary requirements or other less egregious areas. We are particularly interested in the education issues that would come and making sure that everyone is very much on the same page about this new regime if it is introduced.

Mr KELLY: Thank you for your submission. Turning to page 4, in paragraph 2.2 you talk about the suitability of a person to hold an approval, and in the third or fourth paragraph you talk about developing the guidelines of what is expected for an applicant. I think some of those guidelines relate to criminal history et cetera. Would it be fair to say that if you are a practising doctor many of those guidelines would have already been met as part of the registration process and that is something that is checked on annually anyway?

Mr Bowen: I think that would be correct, at least in part. Certainly every year when a doctor completes their registration process through the Australian Health Practitioners Regulation Authority, AHPRA, they are required to make declarations about whether they have any criminal history. I understand that as information is disclosed AHPRA would consider whether that is of any relevance to their healthcare practice. There are also requirements on medical practitioners, if they have been subject to certain criminal charges or have criminal findings against them, they must notify the authority and the authority can take appropriate steps. I would agree with you that some of that—perhaps much of that—would be dealt with by the professional regulator.

Mr KELLY: On page 6, under paragraph 2.5, and elsewhere in your submission you draw attention to the fact that, in relation to this class of medications, if this bill is passed not only would the patient have to be approved but also the doctor would have to be approved. You anticipate some issues around transfer of care if, for example, the patient was approved but the doctor was not. Could you elaborate on that? Would there not be an automatic ethical obligation on the doctor to transfer care for that patient if they were unable to deliver that particular service?

Mr Bowen: I must apologise, I did not hear part of what you said. There is quite an echo on my line.

Mr KELLY: Sorry, I am the furthest from the speaker phone. I am alluding to paragraph 2.5 of your submission. You make the point in a number of places that, in relation to this medication, if this bill is passed both the patient and the doctor will have to be approved. You anticipate there may be some delays in care or there may be no care at all if a patient is approved but the doctor is not. Could you elaborate on that? I would have thought there would be ethical obligations on the doctor to transfer the care of that patient in that situation.

Mr Bowen: Correct, I agree they would need to transfer care. Our concern relates to the additional delay which then arises from that process. If the patient is already approved, there may be a further consequential time period which the department requires to consider whether the new person would be suitable, particularly if they fall outside of those prescribed categories of patients who can receive it. From our perspective, we were wondering whether having a register or a list of practitioners whom the department has already assessed and considered suitable to be prescribing medicinal cannabis would not be a good substitute for this to ensure the prescription can be given without delay if it is thought appropriate and necessary.

Mr KELLY: If this bill passes and a practitioner follows effectively what is in this bill and prescribes according to this bill, there would be no issues from an insurance perspective that would be different for this type of medication to any other type of medication, would there?

Mr Bowen: Ideally, no. The insurance provided is designed to cover normal health care. If the bill were passed and procedures were followed for medicinal cannabis, that would be considered to be part of professionally accepted or normal health care. The difficulty which may arise with that is around the boundaries of it. If there has been a failure to follow proper processes or there are misjudgements for whatever reason, if any of that conduct was found to be criminal—not commenting on the degree of it—that could potentially lead to questions about whether insurance could be provided. Most insurance policies provide exclusions for cover if there has been a finding of a criminal act. There would be a thought in my mind that a practitioner may have failed in a way to comply with the new regime. There are a variety of steps, and failure to take one step which is a breach of the act in various ways would be considered to be a criminal act, and if there was a finding against them in relation to that then they could be left without insurance.

Mr KELLY: A range of people who made submissions to this inquiry and presented evidence are suggesting that anybody should be able to grow this medication and take it at home. If a practitioner was engaging in that practice, based on your previous answer there would be considerable issues for those practitioners in relation to their insurance and protection from prosecution?

Mr Bowen: Would this be the situation if the prescriber used it for their own purposes?

Mr KELLY: Or recommended that a patient go home and grow it and take it as they see fit.

Mr Bowen: Certainly that example you gave of recommending they go home and grow it is something well outside what the regime contemplates. It is outside the TGA process, and I think there would be serious issues for the doctor if they were looking for insurance cover in that situation.

Mr KELLY: In your submission in a number of places you mention concern around the time frames for approval and the approval process. Would you anticipate that the slower time frame would be a feature of establishing a new regime and that as this medication became a more normal part of the tool kit of medical practitioners the approval process would speed up and become more streamlined?

Mr Bowen: I would like to think so. Our particular concern was having the ability to expedite the process if required. It may be that there would be situations where time is not of the essence, but there may be situations where that three months is problematic and it might be better to try and do things within a month. We wonder whether there would be the ability to prioritise or triage applications, but I would like to agree that the process would speed up. I think probably that would come down to having appropriate clinical inputs, how the clinical advisory committee is set up and who is on it. We have made some suggestions in our submission about the composition of that committee.

Mr KELLY: Thank you very much.

Mr JANETZKI: Thank you, Mr Bowen, for your very comprehensive submission. How many policyholders do you have in Queensland?

Mr Bowen: I do not have the numbers in front of me, but I will see if I can provide that information if required. It is a significant number.

Mr JANETZKI: In the hundreds?

Mr Bowen: I would understand it to be at least in the hundreds.

Mr JANETZKI: In the event that the bill is passed, would you consider it likely that there would be premium increases for these policyholders?

Mr Bowen: I could not speak to that. A judgement from our perspective would probably be made next year. We would probably be seeing the experience of what has happened with that over the initial months. It would be too early to give you any meaningful answer about that.

Mr JANETZKI: Has MIGA spoken with any insurers internationally or do you have any relationships with insurers internationally who have previously grappled with this issue legislatively?

Mr Bowen: No, we have not. We are not aware of who would have dealt with this overseas previously.

Mr JANETZKI: In paragraph 1.4 of your submission you speak about potentially being able to assist in relation to certain indemnity issues. As a general comment, can you expand on MIGA's position in respect of that point?

Mr Bowen: I would go back to what I mentioned in response to one of the other members in relation to how we would approach a claim for cover under the policy. If this bill is passed, it sets up a regime that would be considered a normal and accepted practice of health care. It is not something which would necessarily require a specific provision under a policy to deal with. It would only become a problem if there were things outside the regime, potential criminal sanctions.

Mr JANETZKI: Therefore it would be treated as any other claim would be?

Mr Bowen: That is right.

Mr HARPER: Thank you very much, Mr Bowen, for your submission. I wanted to talk to you about paragraph 2.8 in your submission, time frames for decisions. You note that there is a delay in the process of up to three months, or even longer, which is required to determine applications. I trust that you are raising issues there around terminally ill patients, more straightforward or urgent cases. How do you suggest we best tackle this issue in the bill before us?

Mr Bowen: To one degree I wonder if the department, being well prepared for this and using the information they gather, could deal with some of these things and have internal processes in place. Names would come forward of people who have been approved for prescription and they could be kept. If someone makes an application and time is of the essence and they see someone else has been approved, it may be there is an option to involve them in that process to speed up the time frame. In terms of dealing with it under the act, I appreciate there would be some challenges in trying to reduce the time frame for that, at least initially. It may be that an application could be made to QCAT, the Queensland tribunal, for expedition or in urgent cases a case could be brought before the tribunal to make a determination and the department would then have an opportunity to be a party to that application. If the department could not deal with it by its own internal processes, that may be the circuit-breaker to deal with the urgent application.

Mr CRAMP: Mr Bowen, I refer to section 2.16, the final section in your submission. Can you elaborate on what information the CEO would require from, as you put it, patient class prescribers for matters concerning your company? How would that differ from other information? I am just trying to find out how differently you are going to treat this issue as compared to other issues. Is it just standard information that you are after and what is that, or is there something extra you need from patient class prescribers for medical cannabis?

Mr Bowen: I understand your question is directed to, if a patient class prescriber rings one of our lawyers for advice, what would be required to be disclosed?

Mr CRAMP: Yes.

Mr Bowen: We are only considering what would be in the normal course of health care—understanding who the patient is, what their condition is, what approvals have been put in place, what interactions there have been for with department—so we can provide advice about their standing, what they are required to do if they are concerned that they might have breached something and give them some advice about that and potential implications. We appreciate the bill has been drafted quite tightly, and just to avoid concerns about confidentiality, which doctors often have, whether there might be the benefit of having a provision there with information about the process of care, what a doctor has done and information about the patient and approvals obtained can be released to a legal adviser for the purpose of providing advice.

Mr CRAMP: Are you concerned that this bill, in the way it has been put together, will impede that provision of information that you would normally get from your doctors?

Mr Bowen: It is not a primary concern in my mind. I think we deal with legislation where perhaps there may be questions about whether information can be provided. We have been involved with the legislative oversight committee of parliament recently looking at that issue about what can be disclosed to a legal adviser in the context of GPs accessing hospital records and if there are any uncertainties about that. It set up a regime talking about who could say certain information to whom and I guess that is when we start saying, 'We don't want doctors breaching the law in terms of what they say to whom,' but at the same time there is often a bit of an unspoken or even sometimes explicit position that doctors can seek legal advice about their rights and obligations. I guess we just put that forward as a way of making sure we are all on the same page about that and making sure there is no misunderstanding that people can get advice about this as we anticipate there will need to be.

Mr CRAMP: Thank you, Mr Bowen, because that was actually my next question. You said in your second last paragraph that you do foresee health professionals and your members seeking legal advice. Do you mean from your group they would be seeking that legal advice or do you foresee that individual practitioners are going to have to go and seek medical advice for this new regime before they enter into prescribing this medication for their patients?

Mr Bowen: Potentially. I think practitioners looking at this regime might say, 'This is a very new thing. There's a lot of requirements'—at least from their perspective of it—'What do we do?' We would be looking at educating our doctors even before we get to the point of advice on particular situations, saying, 'This is the regime. These are the requirements generally. If you've got specific questions, come to us for advice.' It may be general advice even before they start their involvement, or down the track it would be the more specific advice such as, 'I have patient A. I'm not sure if they're suitable. What's the process?,' or, 'I'm experiencing some delay in obtaining approval. What can I do?,' or, 'I'm being asked for information about this. I'm not sure what's relevant. What should I provide?' They are the scenarios where we would see advice being asked, but I guess it would be both before entering into this sort of situation and after.

Mr CRAMP: Does that differ from any other new regimes that come in? In considering that this will most likely be an S8 drug, would you consider that medical practitioners will be more wary upon entering this area or do you think it is just par for the course of this level of drug?

Mr Bowen: I think there will be a heightened sensitivity around it and an appreciation that there are quite comprehensive legal and documentary requirements for it and that they are important. Sometimes understanding them can be a challenge. Sometimes accessing information can be a challenge. I and my colleagues have found, in assisting doctors who are prescribing S8 or schedule 8 medication, or going through disciplinary processes afterwards, that sometimes there is a desire to do the right thing and an appreciation that these are addictive and serious drugs and careful clinical consideration needs to be given to their need. Sometimes there is not a good awareness of the particular legal requirements—that is, they need to seek approval at this point or they need to seek a renewal of approval or there has been a change in how the medication is provided and they need to seek an approval or they need to speak to this person. With clinicians doing what they are good at day to day they are sometimes not as, I guess, aware or experienced at dealing with those administrative or legal requirements. There can be a desire to get things right, but sometimes they do not know what to get right.

Mr CRAMP: My last question relates to section 2.14 of your submission. You have put in there that consideration should be given to various entities for an expert advisory panel. Noting that you are a lawyer, you note in there that they should be lawyers experienced in both healthcare regulation and criminal law. Would they be represented as individuals or would you consider that they would come in as representatives of groups like yours?

Mr Bowen: You may want individuals, particularly what might be called disinterested individuals who are not likely to be called on to give advice in these situations. I think there might be challenges finding one person who would fit that description of having the right experience in both healthcare regulation and criminal law. That is a small skill set, but certainly there would be people who would fit that bill who would not necessarily be advising doctors on a more frequent basis about what their requirements are and maybe have more of an academic practice. Given the issues around the criminal law and how it interacts with the Drugs Misuse Act, someone who has experience in those issues probably even more so than the healthcare angle would be important to have involved there as well.

CHAIR: Mr Bowen, thank you very much for your time this morning and thank you for the submission from the Medical Insurance Group Australia. We appreciate you taking an interest in the committee's inquiry.

Mr Bowen: Thank you very much.

Proceedings suspended from 10.23 am to 10.38 am

RANSLEY, Mr John, Executive Member, Queensland Council for Civil Liberties

CHAIR: Mr Ransley, thank you for joining us from the Queensland Council for Civil Liberties. Thank you for the submission both on behalf of yourself and the council. Would you like to make a brief opening statement before we open for any questions?

Mr Ransley: I thank you for the opportunity to appear before the committee. The council basically welcomes the legislation as an attempt to provide medicinal cannabis to Queenslanders who really need it. We are particularly interested in the patient class. The insertion of the patient class pathway was a major step forward in making the legislation workable. Our considered opinion is that the big problem with the legislation is that it relies on Commonwealth supply, so there is nothing in the bill that really goes to the problem of supply. We have the experience of Lanai Carter and other people, but particularly Lanai, documenting the fact that importing medicinal cannabis from overseas is extremely difficult and it is made extremely difficult by the Commonwealth department, particularly the TGA. We do not see any solution to that, apart from the way the Victorian legislation has approached the issue.

The Victorian legislation had the benefit of the Victorian Law Reform Commission report, which I think is probably one of the best reports on medicinal cannabis published in Australia so far. They made the point that relying on a TGA approval process does not work, will not work and will never work, basically. That is why they have opted for organising a medicinal cannabis industry in Victoria that will go from cultivation right through to prescription, overseen by the government, with private suppliers wherever appropriate. The council takes the position that that is much more likely to work. We are talking about thousands, if not tens of thousands, of Queenslanders who could possibly benefit. Importing a medicinal cannabis product one by one is just not going to work.

CHAIR: Thank you for that opening comment. I have one overall question about the submission from the council. Certainly it promotes far more open access to medicinal cannabis. From the testimony that we have heard this morning from the College of Physicians and the Australian Medical Association of Queensland, it seems that certainly they support significant regulation, because the efficacy of medicinal cannabis, in their mind, is still untested to such a level—I think it would be fair to say that their comment was to a level where it should be more readily available for doctors to prescribe. Can you comment on that? Obviously there is a very large disconnect between the views of the council and doctors.

Mr Ransley: Only some doctors. We have a great respect for Alex Wodak and Laurence Mather, for example, who have made a submission to this committee. Alex Wodak has been saying for some time that there are over 100 very well designed studies from overseas demonstrating the efficacy and safety and so on of medicinal cannabis products.

The council also would go back to the point where this whole war on drugs started. It is worth making the point that we think that when President Nixon commenced the war on drugs it was purely a political act. It was nothing to do with protecting users of cannabis or, for that matter, heroin, but that is a very small group. It was nothing to do with protecting people from harms associated with cannabis use; it was all about locking those people away so that they would not interfere with his political programs. From the very beginning the war on drugs, in our view and documented by one of President Nixon's very close associates, was a political act. It was nothing to do with the—

CHAIR: Mr Ransley, can I bring you back to the bill that the committee is considering for a moment. You make the comment about the United States and the scheme there, and that obviously the States does not have consistency, either. The committee heard evidence in answer to a question asked, I think, by the deputy chair, about the trials and things that have been done there into the efficacy of the drug. The committee heard from the department that it has not gone through a level similar to the TGA, a Commonwealth system or a federal system, to actually further underpin the efficacy of the use of medicinal cannabis for medical conditions. Do you have any comments in regard to that, hence why we are taking quite a regulated approach to this in Queensland?

Mr Ransley: The Victorian Law Reform Commission made the point that medicinal cannabis has to be dealt with outside of the TGA process. That is the point. That is why they said there is no point going through the TGA process, because that will not work. That is why they set up their legislation in the way that they have set it up. I can quote you the section if you want. The Victorian Law Reform Commission report makes that point very clearly. Medicinal cannabis has to be treated in a class of its own. It has proven to be very safe. There are people who argue that it is not safe and it is a terrible drug and so on, but even the Byrne report, which the Queensland government commissioned and was published last year, makes the point that cannabis is basically a relatively harmless drug.

Mr McARDLE: Mr Ransley, thank you for coming in today and for the submission on behalf of the council. In your opening comments you referred to the Victorian model. I want to confine my question and your answer to that and a comparison to Queensland. You made the comment that Victoria has moved to a state based licensing scheme—those are my words, not yours—whereby cultivation, production and supply take place at a local level. You then refer to the TGA process. Could you tell me the differences you see between the bill as it sits in Queensland and the TGA process involvement in the supply, and how that is perhaps more convoluted than the Victorian model you have referred to?

Mr Ransley: All the evidence we have so far and the experience of Mrs Carter is that the TGA process is extraordinarily bureaucratic and obstructive to the point where it will discourage most people from using that as a means of importing the drug. The only thing that might overturn that is if the medical cannabis clinic in New South Wales—I do not know whether they have appeared before the committee—succeeds in their appeal against the TGA blocking their licence to import. Then they say they will be in a position to supply a CBD product to everyone in Australia which, as far as I understand it, will bypass the Queensland legislation.

The CBD product is schedule 4. If there were a CBD product available in Australia at the moment, which there is not of course, it would be perfectly legal to prescribe. At the moment the TGA is blocking this schedule 4 product from being imported from overseas which is, in our view, quite irrational.

Victoria looked at the TGA process. Clause 103 of the Victorian Law Reform Commission report stated—

A Victorian scheme that requires medicinal cannabis products to be approved by the Therapeutic Goods Administration would reinforce the status quo and not result in any additional approved products being made available to patients for a significant period of time. It follows that ... a regulatory structure needs to be established.

That is what they did in Victoria. I think the Victorian Law Reform Commission had it right that importation does not work. We also have the additional problem that Holland, which is the main producer of medicinal cannabis, does not allow it to be exported to other countries. At the moment there seems to be the possibility of very small amounts being imported from Canada and the US, but the federal administration in the US opposes the export of their product as well. I do not see that importation is ever going to work. We are left with waiting for an Australian cultivation, manufacture and production system to the relevant standard and so on that is going to take years. In the meantime there are lots of people out there with children with intractable epilepsy who could die at any time.

Mr McARDLE: Can I take you to the section of your submission headed 'Terminal illness provision'. I note that it was Mr Cope who signed the submission and not you. That provision deals with the New South Wales model whereby a person who is terminally ill can go to see a doctor, get an authorisation, have a quantity of marijuana on them and have a third party assist. As I understand that regime, the certificate issued only lasts for a period of 12 months then has to be renewed. Registration occurs with the justice department or the health department in New South Wales—I am not certain off-hand which one. Are you advocating that such a provision should occur in this state when a person is deemed terminally ill? A person may be deemed terminally ill but have years of life left in them. Can you comment on that?

Mr Ransley: The problem with the New South Wales system is that it has a very low uptake. The last time I looked there were only about 30 people who had taken up the option. In our opinion the reason is that people do not trust a discretion being granted to the police. That is not sufficient legal protection. They need to have that legislated so that there is a complete defence in law, not a discretion which is left up to local police who may or may not exercise it. We have had examples reported to us where police have busted someone who is using a medicinal cannabis product and have exercised their discretion to arrest or at least record the arrest or in some cases proceed to conviction.

People in that situation are saying that it is all very well to give the police discretion, but they want a law that says very clearly it is legal if a doctor says a person is terminally ill. Even if that might be a matter of years, you have a complete defence. You are absolutely secure and safe from prosecution. That is the only way that provision can work. We advocate that sort of legalisation.

Mr McARDLE: In New South Wales it is not medical cannabis; it is cannabis, per se, that can be used under the scheme, as I understand it. If I am wrong, please let me know. My concern, however, is: is that not in essence the thin edge of the wedge? At what point in time do you stop without proper trials and without proper research and understanding of the impact upon people's lives? Where do you stop from, say, using heroin or cocaine if someone else says, 'This gives me relief and I am terminally ill'?

Mr Ransley: The idea that using cannabis will lead to more serious drugs is an old trope. It has been around for 50 years, as far as I can recall. It has been discredited many, many times. From my personal observations the biggest danger from smoking cannabis is that it leads to smoking tobacco because tobacco is often mixed as a combusting agent. We do not give any credence to that kind of progression. It is not there in the evidence.

You have very small numbers of people using heroin. You have hundreds of thousands of people in Australia using cannabis every week. It has been estimated and quoted in the Victorian Law Reform Commission report that 750,000 people use cannabis every week in Australia which would translate into about 152,000 Queenslanders using cannabis every week. That is a lot of people using it. It is obviously very safe because otherwise emergency departments would be full of people.

Mr HARPER: Thank you very much for your personal submission. I wanted to look at the QCCL's submission around the Victorian model. The opening line of your submission says it all. It states that you prefer 'the Palaszczuk government to legalise cannabis without any restrictions'. What we have heard from some submitters is that if we do not have regulation around it the THC component can be uncontrolled—it can sometimes be high and sometimes cause psychosis—versus the CBD or cannabinoid component, which is what we are trying to extract to give to patients in a medical cannabis trial. Do you have any comments around what previous submitters have said that a high degree of psychosis has been found in long-term cannabis users? Do you think, from our perspective, that we should take a more pragmatic or sensible approach in adopting the trial and controlling and having some regulation around the cannabinoid part of the drug itself?

Mr Ransley: We do not think it is necessary to wait for trials. We think there is plenty of evidence from overseas trials—quoted by Dr Alex Wodax, for example, in his submission—that medicinal cannabis can be very effective for a number of conditions. The CBD product is so safe in hemp oil extracts that it is very hard to understand why it is not legal now. It has moved to schedule 4 for 18 months or so. It would be legal if it were produced in Australia. That is the crazy thing.

We also see a role for high-THC medicinal cannabis products. They have them in the US. They have proven to be very effective in reducing cancer in some cases. What you have in the US and California, where medicinal cannabis is legal, is mainstream medico-legal procedures, prescription and so on with a whole range of different products which are tailored to individual cases. That means somebody with cancer can benefit from a high-THC product which is available in a predictable ratio of four to one or whatever and designed to be appropriate for a particular person.

The old trope about cannabis leading to psychosis is still very controversial. It has not been proved to any scientific level of satisfaction. In any case, it is irrelevant when you are dealing with very small amounts of cannabis like drops of hemp oil or capsules even with a high THC ratio. You are looking at very small amounts. There is no evidence that schizophrenia or psychosis or any of those things are going to be an issue.

My personal view is that if I had teenage children I would not be discouraging them from using cannabis; I would be much more concerned about them binge drinking, because there are proven cognitive and memory effects—quite severe effects—from binge drinking which are much more severe than anybody can ever get from using cannabis.

Mr HARPER: Mr Ransley, you did make comment about the high levels of THC and the effects on cancer patients. Is there any evidence based research to back up that statement in terms of studies?

Mr Ransley: There is. I would have to come back to you on the research. I am going on very strong anecdotal evidence on that one.

Mr HARPER: I will get you to take that on notice. Some submissions stated that the evidence for medicinal cannabis is weak. Is it possible that patients' expectations regarding the usefulness of medicinal cannabis are too high and could patients be disappointed if they try medicinal cannabis and it does not help them?

Mr Ransley: Of course that can happen. That can happen with any medicine. What the council would like to see is the medicinal cannabis being made available for people to try, to see if it helps their condition. That is the bottom line. We want it to be sufficiently legal and sufficiently available in useful forms for people to give it a good go. Of course there will be people for whom it is not suitable, but we have very strong anecdotal evidence that it is incredibly useful for intractable epilepsy in children, for example. That is just one whole group. There were some submissions to this committee documenting that. People say, 'It's like a miracle. The seizures just stop,' and so on. We have very strong anecdotal evidence of that kind. Also, we have very strong evidence that cannabis is very safe. It has never killed anybody, unlike aspirin for example.

Mr HARPER: You made comments like 'give it a go', 'we should see' and 'there is some anecdotal evidence'. I get that. We have seen some reports on media in terms of drug resistant epilepsy in other countries. Do you conclude, though, that we should have a clinical trial and gather more evidence to support those claims? Evidence based research is at the very core of this, I believe. Do you have any final comments on that?

Mr Ransley: Of course we support clinical trials. The problem is that clinical trials which have been flagged in New South Wales, for example, have yet to start. They can take years to complete. At the end of the trials there is a whole parliamentary process or government process of looking at the trials and deciding whether they will accept the recommendations or whatever the trials come up with. We are looking at a process with trials and so on that could take years. Our concern from the council's point of view is that there are a lot of people out there who could benefit from using it right now. Cannabis has been shown to be incredibly safe no matter what way it is used—remarkably safe I think is a better way of putting it—compared to mainstream legal drugs and prescription drugs. Even the Byrne report looking at the medical effects of cannabis came to the same conclusion—that cannabis is remarkably safe.

Mr CRAMP: My question relates to our witnesses last week, and I did refer to this earlier. In the QCCL submission you spoke about the fact that people do not have the skills to adequately grow their own medicinal cannabis. You alluded both in your submission and in your answers that, although it is some years off, it would be highly desirable to see an Australian based industry—possibly a Queensland based industry—which is great for commerce and possibly a great idea for controlling the chemical balances in it. From the QCCL's point of view—you are there to represent the rights of individuals—what is your position on the witnesses last week who were heavily invested in wanting to grow their own medicinal cannabis? Where does the QCCL stand on that in regard to people who are carers for patients or in fact patients themselves standing up and saying, 'We believe that growing cannabis as a mass produced industry won't provide the right chemical balances that we need that we have worked out ourselves.' Where are their rights in all of this?

Mr Ransley: The bottom line for the council is that basically we believe cannabis should be legal anyway. We understand that that is not possible in Queensland at the moment, although we believe it will come. I must say, I have been saying that for about 30 years. Of course we support people growing their own and we would support a provision that would allow that, but the bill does not do that at the moment. What has happened is that Queensland can claim to be the first state legislature to legalise medicinal cannabis as in November 2015, but Victoria has overtaken Queensland in this respect. They are off and running. They have already set up cultivation and so on. It is a great shame from our point of view that Queensland has lost the plot, and that is what we think has happened with this bill.

We support people growing it. The issue with people growing their own versus having a mass produced industry is a genuine one in terms of all of the problems around deciding whether the product is the right product, whether it has the right ratio of THC to CBD and so on, or whether there is no THC or less than two per cent of THC, which is a schedule 4 drug. It requires very sophisticated gas chromatography equipment to sort that out. What people who grow their own are saying is that you have 40 or 50 years of an illegal cannabis industry in Australia. You have people like Mullaways, who provide a product which is said to be very good.

CHAIR: Mr Ransley, we will have to conclude there because we have run out of time to ask you questions. While I have allowed some latitude, supply is obviously not contained in the bill, so we are straying to some degree from the bill. On behalf of the committee, I thank you for your time in coming today to appear on behalf of the Queensland Council for Civil Liberties and also for the submission that was made that I know obviously you had a hand in. Thank you for appearing before the committee today.

HARMER, Mr David, Director, Legislative Policy Unit, Department of Health

FORRESTER, Ms Kathleen, Deputy Director-General, Strategy, Policy and Planning Division, Department of Health

VINCENZINO, Ms Dorothy, Executive Director, Healthcare Regulation Unit, Prevention Division, Department of Health

ZGRAJEWSKI, Mr Mark, Manager, Legislative Policy Unit, Department of Health

CHAIR: Welcome. Thank you very much for coming before the committee again today. Thank you for the response, too, to the issues raised in submissions. That was very appreciated by the committee. The committee wishes to give Queensland Health the chance to clarify any issues that have arisen from submissions or from either of the public hearings, as well as ask officers present here today some questions. Are there issues that you would like to specifically raise or speak to first? Then we will open it up to questions.

Ms Forrester: Thank you, Madam Chair, and the committee for having the department back to speak with you today and to answer your questions at what I believe is the end of your hearings. The department has had the opportunity to consider the submissions made to the committee during its inquiry. There are four issues that we would like to provide some clarifying comments on to assist the committee. Of course we acknowledge that many other issues have been raised and the department will be happy to address these in response to your questions.

The four issues the department would like to address are: first, the concern that the bill is duplicative of the Commonwealth legislation and/or the Therapeutic Goods Administration, or TGA, processes; second, the proposal that it would be preferable for the government to legislate to allow broad access to raw cannabis products, including by permitting users to grow their own medicinal cannabis; third, the view that the bill imposes unnecessary red tape that will prevent patients accessing medicinal cannabis products in a timely way, which is a particularly important consideration for palliative care patients; and, fourth, the reasons for giving the chief executive a discretion to require criminal history checks.

On the issue of duplication, the Commonwealth and states and territories play related and complementary roles in the regulation of medicinal cannabis. The Commonwealth controls what drugs are available for use through the Narcotics Drug Act and the Therapeutic Goods Act. Individual states then regulate patient use of these products—for example, including prescribing and dispensing. For a patient in Queensland to be lawfully supplied with, possess and use a medicinal cannabis product, Commonwealth and Queensland laws must operate together.

It was only when Queensland amended the Health (Drugs and Poisons) Regulation 1996 in December 2015 that it was possible for any patient in Queensland to lawfully use medicinal cannabis, even if supply of the medicinal cannabis product was approved by the TGA. There is, however, a degree of duplication in the information required under the Commonwealth and the state schemes. It is acknowledged that from an applicant's perspective this may appear as duplication of process when applying to the TGA and Queensland for approvals, but it is indeed a duplication of information requested. It is also important to recognise that the TGA and department had and continue to have differing roles and responsibilities. The Department of Health will liaise closely with the TGA to identify ways of ensuring the approval process under both state and Commonwealth schemes can run efficiently and are not unnecessarily duplicative in terms of information requested.

On the issue of raw products, a number of submitters promoted the benefits of using raw cannabis products for therapeutic purposes and preferred botanically derived medicinal cannabis product to synthetic versions. Many of these submitters strongly advocated for the bill to allow the use of homegrown medicinal cannabis. In his explanatory speech and public statements regarding the bill, the minister has made the government's position on this clear. Cannabis, regardless of its form or the purpose for which it is used, is a potentially dangerous drug. The purpose of the bill is to provide a framework for such dangerous drugs to be used safely as part of a patient's overall treatment plan. It is therefore important that any cannabis product used for a therapeutic purpose be cultivated or manufactured in accordance with good agricultural and manufacturing practices. This applies equally to botanical or synthetic products. For this reason, the bill does not enable patients to grow their own cannabis for medicinal purposes because doctors and patients have no certainty about the concentrations of active ingredients in the products they are consuming or prescribing or knowledge about the contaminants to which plant products may have been exposed.

Although the bill allows medical practitioners to prescribe both botanical and synthetic medicinal cannabis products, most synthetic products remain in developmental stage and are unlikely to be available for patient treatment in the foreseeable future. For this reason, it is expected that most approvals granted under the bill will be for botanically derived products.

On the issue of potential delay, a number of submitters argued that the bill will impose unnecessary red tape and believed this will prevent patients from obtaining timely access to medicinal cannabis treatment. The time frames in the bill are the maximum periods within which actions must occur and the department will endeavour to process applications as quickly as possible. The bill also provides two prescriber pathways to accommodate the different classes of patient. I am sure the committee is familiar with those two patient pathways by now.

Finally, on the issue of criminal history reports, some submitters objected to the offence provisions in the bill for unauthorised use of medicinal cannabis and to the discretion of the chief executive to obtain a criminal history report of a patient or medical practitioner before granting approval. The chief executive may elect not to obtain a criminal history report. The bill reflects the government's intent to strike a balance between facilitating treatment with medicinal cannabis products and creating the controls necessary to ensure these products are used safely and not diverted for unlawful purposes.

For this reason, the bill contains important safeguards including criminal penalties for unauthorised use, powers for inspectors to monitor compliance and the discretion to obtain a criminal history report. It is highly unlikely that any eligible patient will be denied medicinal cannabis treatment solely because of their criminal history. Rather, where a criminal history is sought it would inform the types of conditions imposed on the use of medicinal cannabis, such as dispensing restrictions to limit the amount of medicinal cannabis that a patient may possess at any one time to prevent unlawful diversion. My colleagues and I would now be happy to answer any questions.

CHAIR: Thank you very much, Ms Forrester, for those points of clarification. Can I start where you finished, with criminal history checks. What situation did the department envisage could give rise to a criminal history check, given the wording 'may'?

Mr Harmer: The department did not anticipate a specific situation, but, given advice from other agencies about the need for appropriate protections, the capacity to ask for a criminal history check was included. One example might be where there was some reason for the department to suspect that there was some criminal association either from a member of the family or the applicant. In that context the chief executive might ask for a criminal history check. If the criminal history pointed to the fact that there was a criminal history of drug use, the chief executive would have the ability to consider what additional controls might be put in place before approval was granted.

CHAIR: Is that the same as the current environment with other schedule 8 drugs?

Mr Harmer: No, it is not.

CHAIR: I am trying to understand that because other schedule 8 drugs can have a significantly high street value as well. Why are we treating the two differently?

Ms Forrester: One of the key differences in considering other schedule 8 drugs and other narcotic drugs generally is the consideration that medicinal cannabis is perceived in some sections of the community to be a recreational drug and is certainly seen as an accepted drug for use in those contexts and circumstances. We are aiming with this bill to establish a very robust framework that allows all members of the community to clearly differentiate what is a medicinal product which will be a legal use of medicinal cannabis used as part of a medical treatment regime from what is seen by some members of the community as appropriate for use in recreational circumstances. To that extent, we are establishing quite a robust framework to make that delineation clear and to provide clarity for the community at large.

CHAIR: Given that it would be prescribed through a small number of pharmacies which are allowed to do so or a hospital pharmacy, do you feel that perhaps that distinction may already be clear, or is it the view that it may not be?

Ms Forrester: It is the view that it was an important option to have. As I said, it is not a requirement that the chief executive obtain a criminal history check for any application or for all applications that are received, but it certainly gives the chief executive an option if presented with a circumstance where there is information about any of the parties involved in the process to have that criminal history check information.

CHAIR: I do appreciate that your evidence here today is that it would only be used in particular circumstances, perhaps if something gave rise to feeling you needed that additional information. In any submissions the department received or in any discussions, was it ever envisaged that there could be a patient class whose background meant they would not be prescribed medicinal cannabis if it was found or considered to be useful for them?

Ms Forrester: As I said, we consider that circumstance to be unlikely on the basis of a criminal history check alone, but certainly it is considered to be potentially useful information in terms of determining whether conditions needed to be placed on the approval—as I say, in terms of how much of the product might be prescribed at any single point in time.

CHAIR: Doctors themselves have to meet a threshold to be considered an appropriate person. My recollection—please correct me if I am wrong—is that they can also go through a similar process, but do they not already have high threshold checks under AHPRA?

Ms Forrester: Under AHPRA, that is correct. A doctor will be required, as part of their registration process under the national board, to have a criminal history check when they first apply for and are granted registration. In the course of their registration they are required to self-report if they are charged with an offence that is punishable by 12 months imprisonment or more, or convicted or found guilty of an offence punishable by imprisonment in Australia and/or overseas.

When people are required to self-disclose, if that is the circumstance they find themselves in, and equally at the point of renewal of registration they must disclose any changes to their criminal history. You are correct: the registration process does address criminal history requirements. We are just concerned to ensure that, if the chief executive feels they need information that is absolutely accurate at that point in time that they are making a decision, they have a legislative means to obtain that information.

CHAIR: Thank you for that additional information. I really do not yet have clear in my own mind the role that the TGA plays. I very much appreciated your opening comments because they were very helpful. If I was seeing a specialist—and I will choose palliative care as this is something close to my heart—if this was considered to be an option, and it could be a helpful option because obviously time is of the essence and often in short supply, you would go to your specialist. I appreciate it is clear in the bill what the Queensland process would be, but what is the process of the TGA?

Ms Vicenzino: The TGA identifies the product as a therapeutic good and approves that for use. If it is outside of the approved use and you are looking at a product that is not registered, for the product that is identified the TGA goes through a process to ensure that product reaches the right standards for use by that doctor and that particular patient.

CHAIR: The product itself? How much overlay or time do they put into considering the doctor and the patient? You have talked about the process that Queensland Health would be looking at, and I appreciate that you have said there is a duplication of information requested, but how much duplication of consideration of those elements occurs or would occur?

Ms Vicenzino: Basically the TGA considers what the doctor is using it for and assesses that product for that use. Generically, if you want to use it for condition X, is that product of a suitable quality to meet the requirements that the doctor has requested? They ask for similar information but the state would ask for additional information in regard to the condition that the patient is considering—for example, how it will be dispensed, how much is going to be dispensed, how the patient will use that product, and for the period of time what are the expected outcomes.

CHAIR: In the department's consideration of what the process should be to ensure adequate regulation as we work through the process of looking at the efficacy of medicinal cannabis, I would imagine—but I do not want to put words into your mouth—that due consideration was given to ensuring we have an appropriate degree of regulation but we also need as streamlined a process as possible given these are bureaucratic processes that are having to operate side by side and we have people who could be time limited or just very sick.

Ms Forrester: This has been a very active area of legislative activity across a number of states including Queensland and the Commonwealth over the last year particularly. We are aware that there is work that we need to do with the TGA and that we will do with the TGA to identify ways to streamline the processes that we have in place. I reiterate that there are separate roles for the Commonwealth and the state, as I set out in my opening statement. The functions and the decisions that are being made are not the same.

I would also point to the fact that both in the TGA process and in the state process we have aimed to create the patient class type prescriber. Instead of requiring every individual with every application to step through an entire process, both agencies have put in place pathways that allow

groups of authorised prescribers for the TGA or patient class prescribers in Queensland to have a more streamlined approach—in essence, having been once approved therefore being enabled to exercise their professional discretion in the prescription of medicinal cannabis.

I would point to that as an indication that both agencies are keen to ensure that the prescribing and use of medicinal cannabis in a defined set of circumstances is as streamlined and as straightforward as possible, noting that we are talking about the use from the TGA's perspective of an unapproved product which means they will need to step through their processes for endorsing the use of and access to an unapproved product. We are equally keen in Queensland to ensure that we continue to build the evidence base in terms of the use and efficacy of medicinal cannabis.

CHAIR: I will leave the questions I have about the different jurisdictions to the deputy chair, because I imagine he may raise Victoria. I have one final question, because I know we all have many questions and we very much appreciate you being here to clarify. One thing that was raised was a single user pathway and that if an approval came through for a particular level or quantity of a particular product, if that did not work and it was an issue for that patient, they may need to go through the process again to vary that. I think that was a valid and reasonable consideration to raise given that doctors and specialists adjust medication all the time. Could someone speak to that, please?

Mr Harmer: It is an issue that the department needs to consider in terms of the flexibility in the legislation to vary prescriptions. As a preliminary response, I think there is probably sufficient flexibility in the approval that is granted by the chief executive to allow a level of titration by the GP, but that is something I need to go away and confirm in writing, if we can take that on notice.

CHAIR: That would be appreciated.

Mr McARDLE: Thank you very kindly for being here today. I want to thank you for the four points that you have raised and the explanation in regard to each of those points. In March this year the government issued a draft bill and then published a discussion paper. Is that paper still current, or is that really needed to be amended to take into account patient class subscribers as well?

Mr Harmer: My recollection is that the discussion paper does not deal with patient class prescribers.

Mr McARDLE: It does not.

Mr Harmer: That was an aspect of the bill that was developed to reflect a consideration going on in the national framework about rescheduling cannabis, so the bill now includes that patient class prescriber framework to take advantage of rescheduling, should it occur.

Mr McARDLE: Can I drill down a bit further into your comments about information duplication, which I assume means not process duplication. Under the state system, if I am a medical practitioner and I go through the appropriate process to become a prescribed practitioner, the chief executive officer ticks off the whole process, goes through the panel of experts, and they come to a conclusion and I get authorisation to issue the medical cannabis product for my patient, whether it be for palliative care or a child. Do I then go to the TGA under a special access scheme arrangement seeking their consent to issue the drug to me to then deliver to my patient? That is how I understand the process takes place; is that right?

Ms Forrester: That is a reasonable understanding of the process, although I do understand that you can apply first. It does not matter who you apply to first or second.

Mr McARDLE: Yes, you can do it either way but still the TGA process is involved.

Ms Forrester: As I said, that is because the roles of the state and the Commonwealth—

Mr McARDLE: Are still undefined.

Ms Forrester:—are different. They are defined, but they are making decisions about different things. The TGA's starting point is that they have a person seeking to use an unapproved product.

Mr McARDLE: Correct.

Ms Forrester: They have to determine whether they are prepared to grant access and to endorse the use of an unapproved product.

Mr McARDLE: Therefore my question is: as a practitioner, I have gone to the TGA with the state government approval process in train which looks at all the medical aspects of my client and the assessment by the panel and chief executive officer. That then, I assume, is sent down with a form that the TGA requires to be completed. What does the TGA do? Does it simply rubber-stamp that form, or does it need to satisfy itself that the steps undertaken within the state jurisdiction allow it, not just legally but also morally, to issue the drug required by the patient? What I am saying is: is

there a duplication in relation to the assessment of the child or the adult to whom the medical cannabis is going to be given, or is the TGA replicating the special access regime? What does the TGA do in those circumstances? The corollary to my question is: what conversations have taken place between Queensland Health and the TGA to streamline that process, particularly if the TGA is required to undergo its own assessment of the documentation? It may not see the patient, but I would have thought it would need to be certain that what it is going to allow to be issued complies with its own standards as well.

Mr Harmer: I will answer the first part of that question in terms of the TGA's criteria for assessment, and then Dorothy will perhaps address the consultation that has occurred between the department and the TGA.

In answer to your question, yes, the TGA has its own criteria for assessment. They are set out, and it is access to unapproved therapeutic goods via the special access scheme document, which I am happy to table. As the situation stands at the moment, the TGA would go through its own consideration of the patient's details, diagnosis and circumstances and its own consideration of the clinical justification for the drugs being sought. In that sense there is a duplication of the considerations occurring at state and Commonwealth level, but, as Ms Forrester has said, we are working with the TGA, as are other jurisdictions, to streamline that consideration. The end goal would be perhaps we get to a point where, if there is state approved access, the TGA would then endorse that approval.

Ms Forrester: I will just reiterate that it is quite early days in the experience of the TGA and the department working together to approve medicinal cannabis. There is a commitment from both parties to identify ways to streamline arrangements, considering the needs of patients and doctors.

Ms Vicenzino: The TGA in their assessment still has to assess the product and assess that the product meets all the safeguards for good agriculture practice and good manufacturing process. As far as communication between the department and TGA, there are certain confidentiality and privacy issues associated with freely sharing information between the departments without open approval from the patient and the doctor involved, so a way of streamlining is to get prior approval from the patient and the doctor for the sharing of confidential information with regard to the application.

Mr McARDLE: Thank you very much. There is certainly a degree of clinical duplication between the state system and the TGA process in assessing the viability of a drug for a patient. What I am taking from the comments of Mr Harmer is that there is a duplication process.

Ms Forrester: If I may clarify, it is a duplication of the information that is being required by the different agencies. The roles of the Commonwealth and the state are different. They are making different assessments, the starting points are different and they will be making different determinations.

Mr McARDLE: I accept they are different determinations, but they are different determinations based upon the clinical viability of a drug for a patient, are they not? Under a special access scheme the TGA is going to assess whether a patient should be given a particular drug in certain circumstances. The state system certainly puts in place a regime that is then forwarded to the TGA, which then has its own processes. The TGA will assess the clinical viability of the patient and the drug. They may not actually physically examine the patient, but the information coming to them derives to the clinical viability of the patient and the drug they are seeking to be given.

Ms Vicenzino: The TGA also gets additional information from the provider of the actual drug. While they get similar information from the patient and the doctor, they match that against a different set of information that they get from the manufacturer and supplier of the particular substance.

Mr McARDLE: Surely they would assess that against the patient.

Ms Vicenzino: They assess it against the information that the doctor has provided.

Mr McARDLE: Correct. That is exactly my point. They assess that against the patient information.

Ms Vicenzino: The purposes are about the access and supply of the actual particular product. They do not get into how the doctor is going to prescribe that, how that is going to be dispensed and how that is going to be monitored within the state.

Mr McARDLE: Correct, but they will certainly look at whether the drug in those circumstances for that patient is viable. Surely they would have to look at the clinical information and say, 'This makes sense,' or do they simply rubber-stamp it?

Ms Vicenzino: They do have to say, 'Yes, this makes sense.'

Mr McARDLE: Thank you. This may be a very unfair question and I apologise for this, but the Victorian model has moved to legalising cultivation, production and supply. As I understood it—if I am wrong, please let me know—that in part relies upon the Commonwealth bill that went through the House earlier this year that authorised a new TGA model to be used to allow that to occur. That is licensing at state level, which opens up a whole new cultivation and economic basis. That certainly makes a lot of sense. It would tend to overcome in part the TGA threshold we are talking about. Would that be a correct assumption to make?

Ms Forrester: May I just start with the Victorian Law Reform Commission report, which I note was published in August 2015. As I said previously, this is a very active area of legislative activity across jurisdictions, including the Commonwealth and states. I just go back to the report from August last year, and I can point to paragraph 51 of the report. I know that the committee has heard this morning from another witness about the framework that is in place in Victoria and how they do seem to have bypassed the TGA approvals process in relation to manufacture and licensing. It is important to note that the Law Reform Commission report states—

To create a legally stable scheme, all of the options for producing and distributing medicinal cannabis in Victoria would be contingent on the Commonwealth cooperating in either or both of the following ways:

- removing the production and distribution of medicinal cannabis products under the Victorian scheme from the reach of the *Therapeutic Goods Act 1989* (Cth)
- issuing a licence to manufacture cannabis under the *Narcotics Drugs Act 1967* (Cth).

The Law Reform Commission report did turn on the Commonwealth being able to do at least one of those two things to enable the Victorian framework to operate effectively. We understand the Victorian framework has set out to develop its own approach to the manufacturing requirements in its own bill that would meet the requirements of the Narcotic Drugs Act. That is quite a complicated process, but they had a pathway conditional on being able to meet one or both of those requirements and getting agreement from the Commonwealth. As you say, the Commonwealth has since then developed and introduced a bill of its own which did anticipate making some change, but that bill was not completed at the end of the previous government and so its standing is that it was not enacted as legislation.

Mr McARDLE: Thank you very much indeed.

Mr KELLY: I am interested in the issue of criminal history checks, particularly for patients. It would seem to me that if I had a patient that was prescribed something like Endone and we discovered that that patient was somehow keeping their Endone and heading off somewhere and selling it, as a practitioner I would not in any way, shape or form contemplate denying that patient future doses of Endone for pain relief. I would expect that patient would be subject to whatever penalties apply to that behaviour, but it would seem that under this legislation we will have a doctor prescribing medical cannabis which someone needs but an administrator saying, 'We have checked your criminal history and you can't have it.' Can you please elaborate on that for me? That seems to be quite a significant issue that I think many health practitioners would be concerned about.

Ms Forrester: Thank you for the question. I might note that the criminal history check is an option for the chief executive to require. It is certainly not a compulsory piece of information that is provided to the chief executive with every application. The purpose is to ensure there is a complete set of information available to the chief executive and certainly to enable Queensland to have a medicinal cannabis framework that is robust, where the product is used for medicinal purposes as directed by a doctor. It is also intended to ensure the drug is not unduly diverted into illegal activity, as you have said.

Where a criminal history check has been requested by the chief executive and there is some concern given that criminal history, our expectation is not that the medicinal cannabis product would necessarily be denied to that patient but that there would be then potentially additional conditions or specific conditions placed on the prescribing of that product for that particular patient, really to ensure the product is used by the patient and to reduce any risk of the product being diverted into unlawful use.

Mr JANETZKI: Queensland Health responded to a number of the submissions, including one from the Royal Australasian College of Physicians. In the college's submission they had raised some questions about rural, regional and remote Queenslanders to make sure they are not disadvantaged in any way. Queensland Health's response to that submission talked about the existing framework to assist patients in rural areas and said, for example, eHealth. Given the seriousness of this reform, can Queensland Health expand on that existing framework a little in respect of rolling out this potential change to rural, regional and remote Queensland?

Ms Forrester: The committee will be familiar with the dual pathway approach that has been set up in the bill. We do have both the patient prescriber pathway, which we expect to be available to a number of specialists, and the single patient pathway. In developing the bill we were concerned to ensure that people who live in regional and remote areas were not denied access to medicinal cannabis product if their access to those particular groups of specialists was limited by virtue of the fact that they live in a regional and remote area. We were very concerned to ensure that wherever you live there was a pathway in this bill that would enable you to potentially get a prescription for medicinal cannabis. That means that if, by virtue of where you live, your access to the patient class pathway is limited you will have access to the single patient pathway.

What you are referring to in the department's response to eHealth I might refer to as telehealth. We do in some cases use—in growing cases actually—telehealth as a means of ensuring that people in regional and remote areas do have access to medical specialists, so we are really looking at as many options as we can to ensure that people across Queensland have access to particular legislated pathways and, if they still have difficulty accessing a specialist or they need access to a specialist, that something like telehealth enabled through eHealth is available to them.

Mr JANETZKI: Thank you. My second question relates to work that the department may have done already in respect of medical practitioners that, for reasons of conscience or that in their view there may not be sufficient evidence to support medicinal cannabis, may exercise their conscience or discretion not to prescribe medicinal cannabis. I am just wondering whether the department has undertaken any work in contemplating that eventuality.

Ms Vicenzino: The pathway for medicinal cannabis is like any other drug and therefore it is up to the treating medical practitioner, either on the single prescriber or as a class prescriber, to work out what is the best option for their patient. Therefore, the patient, in discussion with their doctor, will determine what best options they have. The other thing that has been mentioned previously is that the department will be looking at the current research and as the body of evidence grows or does not grow in relationship to the particular drugs that are encompassed under the banner of medicinal cannabis. As the body of evidence grows, you may actually find that more doctors are able to prescribe based on the evidence that is in front of them.

Mr HARPER: I am after clarification in terms of nurse practitioners and isolated endorsed nurses prescribing and dispensing medicinal cannabis. Does the department have any issues around that, given QNU's submission?

Mr Harmer: The department did give consideration to this issue. Given that this is a first step in the legislative process, the decision has been taken to limit prescribing to GPs and specialists at this time.

Mr HARPER: I will have to just ask you to repeat why we are not supporting the Victorian model in growing our own. I know you did talk about the agricultural controls, but if I can just move on once we rehash that as a state. Where are we looking to source it from, given some of the witnesses we have heard talked about supply issues from overseas?

Ms Forrester: Certainly there is some product available from overseas and the clinical trials that have been announced in Queensland will be using a product sourced from overseas. In addition, the department has been active in engaging with the agricultural sector across Queensland and has conducted nine round tables to have conversations with people who may potentially be interested in growing medicinal cannabis once the Commonwealth legislation relating to licensing and permit of production and manufacturing is settled and has been endorsed.

Just to clarify, I was not intending to say that the department does not support the production of medicinal cannabis product in Queensland but simply to say that the mechanism that Victoria has put in place depended on the Commonwealth agreeing to make particular decisions, and quite significant decisions, in August 2015. We are quite keen to see the Commonwealth settle its legislation and enable an industry to be considered in Queensland, and for that reason we have been holding round tables to ensure that people in Queensland are aware of the status of the development and potential development of the sector as well as being aware of the roles of the Commonwealth and the state into the future.

CHAIR: Has the Commonwealth rescheduled medicinal cannabis from a nine to an eight?

Ms Vicenzino: Not as yet.

CHAIR: Will that have any implications for the legislation if that does not occur? Do we understand there is an intention not to do it or it just has not happened?

Mr Harmer: Just in terms of the impacts for this legislation, medicinal cannabis is defined in such a way that the bill will operate regardless of how it is scheduled, so there are no impacts that flow to the bill from rescheduling. What it may do, however, is make the patient class prescriber pathway more effective.

CHAIR: Thank you. My colleague the member for Toowoomba South mentioned the Royal Australasian College of Physicians who appeared this morning. It was interesting to me that their submission actually in some regard proposed a more restrictive regime than the department has proposed, so I appreciate that it appears that you have tried to balance community concern and access et cetera with these bodies. The argument they make is that they felt that if a GP was to be involved in accessing and prescribing that should actually occur—I think their language was this—as a dual system. Quickly looking at their submission, they say that the specialist should make the application for approval if they had one of the proposed conditions under the act as they would be in a better position to adjust the patient's treatment regime. I think that comes back to your earlier comments that you are going to look at flexibility under the legislation, but what was the thinking behind making GPs also have that second pathway, which I think you mentioned came up in consultation?

Ms Forrester: What we do have is the single patient pathway that would enable GPs to apply to the chief executive to obtain authority to use medicinal cannabis for an individual patient. Some of the consideration, as I said, was to enable people living in rural and remote areas who may have access to a GP but not easy access to a specialist to be prescribed medicinal cannabis. The other factor that will be a relevant consideration, and potentially a support to GPs who are prescribing medicinal cannabis, is the expert panel that operates in an advisory capacity and is established on that case-by-case basis to provide advice to the chief executive in making decisions, so there is in all pathways access to expert advice which will be available for GPs seeking to get approval for a patient to access medicinal cannabis.

CHAIR: Thank you.

Mr McARDLE: I do not want to go back over what we discussed. Let us accept that there are two bodies—one state, one federal—that have a role to play. Inherent in that is the TGA's right to refuse an application, is it not?

Ms Forrester: Yes. They are required to review access to a particular drug.

Mr McARDLE: Under the Queensland legislation, there is a review process for continual use of a drug on a patient in Queensland; is that correct? I am not making a statement; I am asking the question.

Ms Forrester: Not as you have described it. I do not believe that there is a review process in place that is linked to the length of time that a patient has been prescribed the drug.

Mr Harmer: Just to clarify, approvals are granted for one year at a time.

Mr McARDLE: Yes, that is fine. That will therefore mean that after the one-year period I as a general practitioner or a specialist would go back again to the TGA for the issuance of that drug for a further 12 months. I take it that process also entails me going through the state system to satisfy the requirement of the health department and the chief executive officer. That process goes on for quite some time and every 12 months you start the whole clock again, do you not?

Mr Harmer: It is true to say that the applications need to be made again, but it is important to bear in mind that for the second and subsequent applications most of the information that was needed to make the decision is already held by both the department and the TGA, so subsequent applications are likely to be processed considerably more quickly than the first approval.

Mr McARDLE: Often these medications have to be modified as time goes by because of various circumstances. With regard to the process involved in modifying a drug issued or approved by the TGA ultimately, does that involve the TGA yet again in the process of assessing the modification required and then approving the issuance of a drug that is in essence a different drug but perhaps with the same title?

Mr Harmer: This goes to the question I took on notice earlier, so perhaps I can answer that while I am doing this. In Queensland, when an approval is granted it is granted for a specific dosage, so variations to the Queensland approval are obtained by applying again to the chief executive and then having the approval varied, and there are specific provisions in our legislation that allow for minor variations to an approval. In answer to the question with respect to the TGA, the TGA also approves a specific drug and usage so, yes, there would need to be a variation to the TGA's approval.

Mr McARDLE: You use the word 'dosage', and I accept what you mean by that word. Does that also incorporate the components? The word 'dosage' to me is quantity whereas the components are quite a different matter. You use the word 'dosage'; I am using the word 'component'. Are you using them in an interchangeable manner?

Mr Harmer: No, I am not. Just to clarify for the committee, I am assuming that both the state and the Commonwealth will approve the product that is being used in all of its components and will also approve the amount of the product that may be used. Does that answer the question?

Mr McARDLE: It does, so it is the dosage that has to be varied by the TGA process as well?

Mr Harmer: In my understanding, yes.

Mr McARDLE: Thank you very much.

CHAIR: You did take my question on notice. I should clarify also that 'dosage' was amount, but it was also components given. We appreciate as a committee that medicinal cannabis is different to other opiates that may not have as many complex components.

The time allocated for this public hearing has expired. If members require further information, we will contact you. At least one question on notice has been taken. The secretariat will contact you to confirm the question taken and when the response is due. I thank each of the representatives from Queensland Health for coming again today. We found it very helpful to be able to further clarify these points with you. I declare this hearing closed.

Committee adjourned at 11.59 am